



PTO/SB/08a/b (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet	1	of	4	Attorney Docket Number	BBI-190
-------	---	----	---	------------------------	---------

**Complete if Known**

Application Number	10/693,233
Filing Date	October 24, 2003
First Named Inventor	Zehra Kaymakcalan
Art Unit	1644
Examiner Name	A.R. Chaudhuri

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
ZS	A1	5,231,024	07-27-1993	Moeller <i>et al.</i>	
	A2	5,698,195	12-16-1997	Le <i>et al.</i>	
	A3	5,795,967	08-18-1998	Aggarwal <i>et al.</i>	
	A4	5,859,205	01-12-1999	Adair <i>et al.</i>	
	A5	5,877,293	03-02-1999	Adair <i>et al.</i>	
	A6	5,929,212	07-27-1999	Jolliffe <i>et al.</i>	
	A7	5,945,098	08-31-1999	Sarno <i>et al.</i>	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
ZS	A8	EP 101 681 B1	03-07-1984	Rockefeller University		
	A9	EP 186 833 B2	07-09-1986	Yeda Research & Development		
	A10	EP 212 489 B1	03-04-1987	Rockefeller University		
	A11	EP 351 789 A2	01-24-1990	Chiron Corp.		
	A12	EP 366 043 A1	05-02-1990	Otsuka Pharmaceutical Co.		
	A13	WO 91/02078 A1	02-21-1991	Peptide Technology		
	A14	EP 492 448 A1	07-01-1992	Farmitalia Carlo Erba		
	A15	WO 92/11383 A1	07-09-1992	Celltech Ltd.		
	A16	WO 92/16553 A1	10-01-1992	New York University		
	A17	WO 93/06213 A1	04-01-1993	Medical Research Council		
	A18	WO 93/11793 A1	06-24-1993	Schering Corp.		

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature	/Zachary Skelding/	Date Considered	07/13/2006
--------------------	--------------------	-----------------	------------

Substitute for form 1449A/B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/693,233
				Filing Date	October 24, 2003
				First Named Inventor	Zehra Kaymakcalan
				Art Unit	1644
				Examiner Name	A.R. Chaudhuri
Sheet	2	of	4	Attorney Docket Number	BBI-190

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
Z.S.	B1	5,994,510	11-30-1999	Adair <i>et al.</i>	
	B2	6,015,557	01-18-2000	Tobinick <i>et al.</i>	
	B3	6,024,938	02-15-2000	Corbo <i>et al.</i>	
	B4	6,090,382	07-18-2000	Salfeld <i>et al.</i>	
	B5	6,171,586 B1	01-09-2001	Lam <i>et al.</i>	
	B6	6,214,870 B1	04-10-2001	McClure <i>et al.</i>	
	B7	6,235,281 B1	05-22-2001	Stenzel <i>et al.</i>	
	B8	6,258,562 B1	06-10-2001	Salfeld <i>et al.</i>	
	B9	6,270,766 B1	08-07-2001	Feldman <i>et al.</i>	
	B10	6,423,321 B2	07-23-2002	Tobinick <i>et al.</i>	
	B11	6,509,015 B1	01-21-2003	Salfeld <i>et al.</i>	
	B12	6,537,549 B2	03-25-2003	Tobinick	
	B13	2003/0124119 A1	07-03-2003	Yamazaki, <i>et al.</i>	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>3</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
Z.S.	B14	EP 614 984 A2	09-14-1994	Miles Inc.		
	B15	GB 2 279 077	12-21-1994	Celltech Ltd.		
	B16	WO 94/29347 A1	12-22-1994	Therapeutic Antibodies Inc.		
	B17	EP 659 766 A1	06-28-1995	Schering-Plough		
	B18	WO 95/23813	09-08-1995	Merck & Co., Inc.		
	B19	WO 97/04801 A1	02-13-1997	Genentech, Inc.		
	B20	WO 97/29131 A1	08-14-1997	BASF AG		
	B21	WO 98/56418 A1	12-17-1998	Genentech, Inc.		
	B22	EP 1 174 148 A1	01-23-2002	Yamanouchi Pharma Co.		
	B23	WO 02/12502 A2	02-14-2002	Centocor, Inc.		
	B24	EP 1 254 666 A1	11-06-2002	Chugai Seiyaku Kabushiki		
	B25	WO 02/100330 A2	12-19-2002	Abbott Laboratories		
	B26	WO 2004/004633 A2	01-15-2004	Abbott Laboratories		
	B27	WO 2004/09776 A2	01-29-2004	Abbott Laboratories		
	B28	WO 2004/016286 A2	02-26-2004	Abbott Laboratories		
	B29	WO 2004/037205 A2	05-06-2004	Abbott Biotechnology Ltd.		

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature	/Zachary Skelding/	Date Considered	07/13/2006
--------------------	--------------------	-----------------	------------

Substitute for form 1449A/B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/693,233
				Filing Date	October 24, 2003
				First Named Inventor	Zehra Kaymakcalan
				Art Unit	1644
				Examiner Name	A.R. Chaudhuri
Sheet	3	of	4	Attorney Docket Number	BBI-190

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
ZS	C1	Barbuto <i>et al.</i> Production of Neutralizing Antibodies to Tumor Necrosis Factor by Human Tumor-Infiltrating B Lymphocytes. Proc. Am. Assoc. Cancer Res. 1993. 34:487, Abstract 2904.	
	C2	Bendtzen <i>et al.</i> Auto-Antibodies to IL-1 $\beta$ and TNF $\alpha$ in Normal Individuals and in Infectious and Immunoinflammatory Disorders. The Physiological and Pathological Effects of Cytokines. Wiley-Liss, Inc., 1990, pp. 447-452.	
	C3	Boyle <i>et al.</i> A novel monoclonal human IgM autoantibody which binds recombinant human and mouse tumor necrosis factor-alpha. Cell Immunol. 1993 Dec;152(2):556-68.	
	C4	Boyle <i>et al.</i> The B5 monoclonal human autoantibody binds to cell surface TNF alpha on human lymphoid cells and cell lines and appears to recognize a novel epitope. Cell Immunol. 1993 Dec;152(2):569-81.	
	C5	Chow <i>et al.</i> Effect of Monoclonal Antibody on Human Tumor Necrosis Factor (TNF MAb) on TNF $\alpha$ , IL-1 $\beta$ , and IL-6 Levels in Patients with Sepsis Syndrome. Clinical Research. 1994. 42(2):299A.	
	C6	Cleland <i>et al.</i> A specific molar ratio of stabilizer to protein is required for storage stability of a lyophilized monoclonal antibody. J Pharm Sci. 2001 Mar;90(3):310-21.	
	C7	Cox <i>et al.</i> A directory of human germ-line V kappa segments reveals a strong bias in their usage. Eur J Immunol. 1994 Apr;24(4):827-36.	
	C8	Elliott <i>et al.</i> Treatment of rheumatoid arthritis with chimeric monoclonal antibodies to tumor necrosis factor alpha. Arthritis Rheum. 1993 Dec;36(12):1681-90.	
	C9	Fomsgaard <i>et al.</i> Auto-antibodies to tumour necrosis factor alpha in healthy humans and patients with inflammatory diseases and gram-negative bacterial infections. Scand J Immunol. 1989 Aug;30(2):219-23.	
	C10	Griffiths <i>et al.</i> Human anti-self antibodies with high specificity from phage display libraries. EMBO J. 1993 Feb;12(2):725-34.	
	C11	Hillgren <i>et al.</i> Protection mechanism of Tween 80 during freeze-thawing of a model protein, LDH. Int J Pharm. 2002 Apr 26;237(1-2):57-69.	
	C12	Huse <i>et al.</i> Generation of a large combinatorial library of the immunoglobulin repertoire in phage lambda. Science. 1989 Dec 8;246(4935):1275-81.	
	C13	Kempner <i>et al.</i> Preliminary Results of Early Clinical Trials with the Fully Human Anti-TNF $\alpha$ Monoclonal Antibody D2E7 Annual Rheumatoid Disease. 1999. 58(1):170-172.	
	C14	Lerner <i>et al.</i> Antibodies without immunization. Science. 1992 Nov 20;258(5086):1313-4.	
	C15	Leusch <i>et al.</i> Failure to demonstrate TNF alpha-specific autoantibodies in human sera by ELISA and western blot. J Immunol Methods. 1991 May 17;139(1):145-7.	
	C16	Lewis <i>et al.</i> J. Cell. Biochem. 1994. 18D:215.	
	C17	Marks <i>et al.</i> By-passing immunization. Human antibodies from V-gene libraries displayed on phage. J Mol Biol. 1991 Dec 5;222(3):581-97.	
V	C18	Möller <i>et al.</i> Monoclonal antibodies to human tumor necrosis factor alpha: in vitro and in vivo application. Cytokine. 1990 May;2(3):162-9.	

Examiner Signature	/Zachary Skelding/	Date Considered	07/13/2006
-----------------------	--------------------	--------------------	------------

Substitute for form 1449A/B/PTO				<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				Application Number	10/693,233
				Filing Date	October 24, 2003
				First Named Inventor	Zehra Kaymakcalan
				Art Unit	1644
				Examiner Name	A.R. Chaudhuri
Sheet	4	of	4	Attorney Docket Number	BBI-190

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
ZS	D1	Tomlinson <i>et al.</i> The structural repertoire of the human V kappa domain. EMBO J. 1995 Sep 15;14(18):4628-38.	
↓	D2	Tomlinson <i>et al.</i> The repertoire of human germline VH sequences reveals about fifty groups of VH segments with different hypervariable loops. J Mol Biol. 1992 Oct 5;227(3):776-98.	
	D3	Tracey <i>et al.</i> Tumor necrosis factor: a pleiotropic cytokine and therapeutic target. Annu Rev Med. 1994;45:491-503.	
	D4	Winter <i>et al.</i> Humanized antibodies. Immunol Today. 1993 Jun;14(6):243-6.	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature	/Zachary Skelding/	Date Considered	07/13/2006
-----------------------	--------------------	--------------------	------------



<b>Substitute for form 1449A/B/PTO</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)			<b>Complete if Known</b>		
			Application Number	10/693233-Conf. #1420	
			Filing Date	October 24, 2003	
			First Named Inventor	Zehra KAYMAKCALAN	
			Art Unit	1644	
			Examiner Name	<del>H. T. Ouspenski</del> Z. SKELDING 6	
Sheet	1	of	1	Attorney Docket Number	BBI-190RCE

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
ZS	F1*	US-20010026801-A1	03-25-2003	Tobinick	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. \* CITE NO.: Those application(s) which are marked with an single asterisk (\*) next to the Cite No. are not supplied (under 37 CFR 1.98(a)(2)(iii)) because that application was filed after June 30, 2003 or is available in the IFW. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		T <sup>2</sup>
ZS	F2	Baugh, John A. et al, "Mechanisms for modulating TNF $\alpha$ in immune and inflammatory disease," <i>Current Opinion in Drug Discovery &amp; Development</i> , Vol. 4(5):635-650 (2001)		
ZS	F3	Elliott, Michael J. et al, "Randomised double-blind comparison of chimeric monoclonal antibody to tumour necrosis factor $\alpha$ (cA2) versus placebo in rheumatoid arthritis," <i>Lancet</i> , Vol. 344:1105-1110 (1994)		
ZS	F4	European Search Report for Application No. 03809644.2-2107, dated March 30, 2006		

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature	/Zachary Skelding/	Date Considered	07/09/2006
-----------------------	--------------------	--------------------	------------